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10/599,555	10/01/2006	Robert Desbrandes		1774

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GIVARLAIS, FR-03190
FRANCE

EXAMINER

PURINTON, BROOKE J

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2881

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,555	Applicant(s) DESBRANDES ET AL.	
	Examiner Brooke Purinton	Art Unit 2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-17 and 19-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5,8-17 and 19-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/29/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-5, 8-17, 19-42 have been considered but are moot in view of the new ground(s) of rejection. Furthermore, examiner apologizes but the statutory response period of one month for restrictions cannot be altered, since it is a legal issue, and non-discretionary.

Response to Amendment

Applicant is reminded of the formalities for amendments.

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: **(Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered)**.

Election/Restrictions

The restriction requirement of 12/30/2009 is withdrawn.

Claim Objections

Claims 1-42 are objected to because of the following informalities:

“Comprising of an” should be simply “comprising an”

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5,8-17,19-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for measuring a variable half life, does not reasonably provide enablement for ensuring that the excited isomer nuclide is entangled via quantum entangled particles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to create the invention commensurate in scope with these claims.

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There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The rejection dated 9/15/2008 discussing Julsgaard et al.'s attempt to entangle samples, albeit collectively to a gas of atoms, shows the complex state of the art. Barring any other prior art published articles in peer reviewed journals, which a search by the examiner has failed to turn up, a person of ordinary skill would not know how to have ensured that a sample of metastable isomer nuclides would have been entangled. Thus, the nature of the invention in view of the state of the prior art and the level of one of ordinary skill all point to an undue experimentation factor in the instant application.

Absent any data proving the existence of pairs of entangled isomer nuclides, the method is not well established or credible. No basic research program known to a person of ordinary skill in the art at the time of the invention provides the knowledge of how to create and subsequently ascertain whether excited isomer nuclides are entangled or not without undue experimentation. The annex provided by applicant fail to show this feature, since the correlation of half life to time does not demonstrate quantum entanglement on a microscopic level, just a property of the system on a macroscopic level. There is likewise no evidence that proves the behavior of the substance is due to entanglement of the isomer nuclide particles and not to some other mechanism. Therefore, since the claims recite "entangled" samples, this limitation was not enabled sufficiently for one of ordinary skill in the art at the time of the

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invention. For the claims to be fully enabled, the applicant has to know which particles are part of a pair which are "entangled" and be able to identify these parts as being in the "entangled" sample, since that is the claim limitation, and not just that there is some probabilistic result.

Claims 25-27 and 30-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Indium (115In49m), it does not reasonably provide enablement for Niobium (93Nb41m), Cadmium (111Cd48m), Cadmium (113Cd48m), Cesium (135Cs55m), Tin (117Sn50m), Tin (119Sn50m), Tellurium (125Te52m), Xenon (129Xe54m), Xenon (131Xe54m), Hafnium (178Hf72m), Hafnium (179Hf72m), Iridium (193Ir77m), and Platinum (195Pt78m). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to create the invention commensurate in scope with these claims.

Claims 1-5,8-17,19-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See above discussion.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least some nuclei" in claim 10 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How much is some?

The term "'entangled" sample" in claim 1 and 10 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Entangled being in quotation marks would have some special meaning not apparent from the claims. In reading claim 1, and then claim 5, the broadest reasonable interpretation

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could be that they are entangled by being a mixture of several isomer nuclides. Examiner will read this as best understood.

Claims 12-17, 40 provides for the use of the product of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-17 and 40 (since 18 is still withdrawn as per a prior amendment) are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

Claim 22 of this application conflict with claim 59 of Application No. 10/599868. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 10 and 22 are provisionally rejected on the ground of nonstatutory double patenting over claim 59 of copending Application No. 10/599868. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

10/599555 – Claim 10	10/599868- Claim 59
10) Manufacturing process of a product comprising	Method of manufacturing a system of entangled

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of an "entangled" sample characterized by irradiation	samples comprising the following steps
in that one prepares a product comprising of a sample containing at least some nuclei of at least one sort of isomer nuclides having at least one metastable state,	One prepares together samples containing nuclei of at least one kind of isomer nuclides having a at least one metastable state,
by means of gamma rays comprising at least some groups of entangled gamma rays, at least some of said groups of entangled gamma rays being of a sufficient energy to excite some of said nuclei of said isomer nuclide to at least one said metastable state, the excited isomer nuclei that are produced being qualified in the continuation as excited isomer nuclide of said "entangled" sample, except where said sort of isomer nuclides is Niobium (99Nb41).	(b) one proceeds to the irradiation by means of gamma rays, at least partly entangled, of a sufficient energy to excite certain of the aforesaid nuclei to at least one metastable state, said entangled gamma rays forming groups which are generated, for example, either by a source of gamma rays emitted in a cascade, or by a generator of gamma rays coming from the Bremsstrahlung of accelerated particles, the groups of said gamma rays, when they are entangled, exciting and transferring their entanglement to the corresponding said nuclei distributed in said samples irradiated together and forming the separate entangled samples of the aforesaid system of entangled samples.
Claim 22) Manufacturing process according to claim 10, in which the aforementioned groups of entangled gamma rays are produced by a generator of gamma rays coming from the Bremsstrahlung of accelerated particles	

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Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-9, 25-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herhleln et al. (5674177) in view of Tam et al. (6685618).

Regarding Claim 1, Herhleln teaches a product comprising an "entangled" (mixed) sample containing at least one sort of nuclides in which at least one said sort of excited isomer nuclides has at least one state being able of deexciting by emitting rays (radioactive nuclide, 1, 11) characterized in that the measurable half-life, called thereafter the "variable" half-life, on at least one said sort of nuclides of said "entangled" sample, is variable, the initial said "variable" half-life of the aforesaid sort of nuclides being strictly lower than the constant half- life of the corresponding normal sort of metastable isomer nuclides, said constant half- life thereafter being called the theoretical half-life, and the value of the said "variable" half-life of the aforesaid sort of excited isomer nuclides varying from the value of the said initial "variable" half-life to the value of the said theoretical half-life, then being higher than the value of the aforesaid theoretical half-life (2, 15-20), except where said sort of excited isomer nuclides is Niobium (99Nb41m) (not mentioned).

Herhleln fails to teach wherein the nuclide is an excited isomer nuclide capable of deexcitation by emitting gamma rays.

However, Tam et al. states that during a radiation delivery source, an isotope that emits gamma rays is chosen for a medical purpose, and that various isotopes known in the art can be chosen.

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Modification would have entailed choosing an excited isomer nuclide with a metastable state that can deexcite by emitting gamma rays.

It would have been an obvious modification to a person of ordinary skill in the art at the time of the invention to have made since it would have enabled more flexibility in tailoring the material to the medical needs and time line of the operator, as well as being able to utilize different materials that were on hand at the time.

Claims 2-5, 8, 9, 25-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hehrlein and Tam as applied to claim 1 above, and further in view of Baldwin (3234099).

Regarding Claim 2 and 25-39, Hehrlein and Tam teach the "entangled" sample according to claim 1.

They fail to teach wherein said sort of excited isomer nuclides is Niobium ($^{93}\text{Nb}41\text{m}$), Cadmium ($^{111}\text{Cd}48\text{m}$), Cadmium ($^{113}\text{Cd}48\text{m}$), Cesium ($^{135}\text{Cs}55\text{m}$), Indium ($^{115}\text{In}49\text{m}$), Tin ($^{117}\text{Sn}50\text{m}$), Tin ($^{119}\text{Sn}50\text{m}$), Tellurium ($^{125}\text{Te}52\text{m}$), Xenon ($^{129}\text{Xe}54\text{m}$), Xenon ($^{131}\text{Xe}54\text{m}$), Hafnium ($^{178}\text{Hf}72\text{m}$), Hafnium ($^{179}\text{Hf}72\text{m}$), Iridium ($^{193}\text{Ir}77\text{m}$), or Platinum ($^{195}\text{Pt}78\text{m}$).

Baldwin et al. teach excited isomer nuclides including ^{131}Xe , and others (see Figure 1).

Modification would have entailed using some of the excited isomer nuclides of Baldwin in the apparatus of Hehrlein and Tam, or any other excited isomer nuclides known in the art.

It would have been an obvious modification to a person of ordinary skill in the art to have made since it would have enabled the operator more flexibility in the choice of substance. It has been held to be within the ordinary skill of a worker in the art to select a known material on the basis of its suitability for the intended use, in this case, exposing a medical device to radioactivity. This was also mentioned in Tam "isotopes...can be chosen by one skilled in the art to serve the needs of a particular application" (11, 30-55).

Regarding Claim 3, Hehrlein, Tam and Baldwin teach the product according to claim 1 further characterized in that said "entangled" sample comprises said excited nuclei of at least one kind of said excited isomer nuclides being radioactive isotopes (see Baldwin, table 1).

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Regarding Claim 4, Hehrlein, Tam and Baldwin teach the product according to claim 2 further characterized in that said "entangled" sample, comprising said sort of excited isomer nuclides, is in any physical or any chemical form, for example in the form of solid in sheet or powder, or in the form of fluid or gas (see Hehrlein, Col. 3-4).

Regarding Claim 5, Hehrlein, Tam and Baldwin teach the product according to claim 2 further characterized in that said "entangled" sample is in the form of alloys, mixtures, or chemical compounds (See Hehrlen, col. 1, mixtures)

Regarding Claim 8, Hehrlein, Tam and Baldwin teach the product according to claim 2 further characterized in that said "entangled" sample contains excited nuclei from at least two sorts of said excited isomer nuclides (Hehrlein, 2, 25-29).

Regarding Claim 9, Hehrlein, Tam and Baldwin teach the product according to claim 2 further characterized in that said "entangled" sample contains excited nuclei from at least one sort of excited isomer nuclides in at least two said metastable states (Hehrlein, 2, 29-32).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

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If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If prosecution in an application is closed, an applicant may request continued examination of the application as detailed in MPEP 706.07(h).

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brooke Purinton whose telephone number is 571.270.5384. The examiner can normally be reached on Monday - Friday 7h30-5h00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571.272.2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. P./
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